Page -4-

## Remarks

Claims 1 to 11 are currently pending in the present application. Claims 1, 3, and 5 to 11 have been amended herein in response to the Action.

In respect of the Examiner's objections and rejections, the Applicant comments as follows:

## Rejection under 35 USC § 112

Claims 1 to 11 currently stand as being rejected under 35 USC 112, second paragraph as being indefinite for use of the phrase "having a predetermined milk fat content". In particular, the Examiner has objected to the word "predetermined" and states that it is unclear how this content is determined and what range constitutes the weight content.

The Applicant respectfully traverses this rejection. The actual amount of milk fat can vary to be any conceivable values that might be practical. As such, the liquid milk can have a first milk fat content, the dried milk powder can have a second milk fat value, and the condensed milk mixture will have a milk fat value which can be targeted, and which is dependent on whatever values are selected for the first and second milk fat content. As such, as long as suitable first and second milk fat content values have been selected, or predetermined, the skilled artisan will clearly be able to produce a condensed milk mixture having the predetermined values.

The Examiner has inherently acknowledged this by stating that for examination purposes, it will "be assumed that any milk fat content would be sufficient for both components". This assumption is correct, and would be understood by the skilled artisan.

Clearly, the skilled artisan would understand that if a low milk fat condensed milk is desired, the milk fat content of the liquid milk and powdered milk would also have to be low. Suitable values for the fat levels for the first and second predetermined fat contents can be easily calculated in order to provide a predetermined amount of milk fat which will be present in the final milk mixture. As such, the skilled artisan would easily understand the phrase "having a predetermined milk fat content" as used in, *inter alia*, Claim 1. As such, the Applicant contends that Claims 1 to 11 are in compliance with Section 112, in respect of this phrase.

Claim 8 also stands rejected under 35 USC § 112, second paragraph on the basis that the

phrase "wherein said first and second predetermined milk fat contents" is not recited in Claim 7. In response, the Applicant has amended Claims 7 and 8 to refer directly to the milk fat content of the milk mixture, and has therefore removed the objected phrase.

As such, the Applicant contends that the rejection of the claims under 35 USC § 112 should now be withdrawn.

## Rejection under 35 USC §103

Claims 1 to 11 currently stand as being rejected under 35 USC §103(a) as being unpatentable over Hatmaker (US 1626818) in view of Robinson (US 3643586), MooMilk FAQ, and FDA (21 CFR 131.110 and 131.120) The Applicant respectfully traverses this rejection, and provides the following comments.

Hatmaker provides a method for the making condensed milk which comprises taking fresh milk and adding to it, dried powdered milk in order to prepare a condensed milk product. This is done at a temperature of between 100°F and 125°F. However, the Hatmaker process differs from the process described and claimed in the present application in at least two aspects.

First, Hatmaker uses "fresh warm natural milk" (Page 1, line 58, Claim 1). This "natural milk" material would obviously contain milk fats, which eliminates the ability of the user to completely control the milk fat content of the condensed milk mixture. For example, if a condensed milk with 0% milk fats was desired, this would not be possible with the process of Hatmaker since the fresh warm natural milk would contain some milk fat that would be present in the final product, regardless of the powdered milk material used.

Second, and more importantly, Hatmaker teaches away from the process of the present invention when he discloses mixing the two materials at elevated temperatures of between 100°F and 125°F. For the fresh (warm) natural milk material used by Hatmaker, the increase in temperature to this specified level, may not be significant. However, in the process of the present invention, the liquid milk may be milk that has already been cooled and stored at much lower temperatures (e.g. 40°F, or lower), and thus, re-heating the liquid milk to the temperature range taught by Hatmaker would be undesirable.

As such, the Applicant has provided a novel process that provides greater control over the

fat content level of the condensed milk mixture, and provides an easier process that eliminates the need to heat the liquid milk used in the preparation of the condensed milk mixture.

Further, while it is noted that Hatmaker may not definitively state that these 100°F plus temperature range is essential, his description clearly leads away from the temperature ranges used by the Applicant. For example, Hatmaker states: (i) that it is preferred that the liquid milk is "moderately heated" (Page 1, line 12); (ii) that it is preferred that the liquid milk has "a temperature a few degrees higher than it had when it came from the cow" (Page 1, line 23); (iii) that "the fresh dried milk is readily incorporated with fresh warm natural milk" (Page 1, line 58); and (iv) that the liquid milk "should be warmed between 100 and 125 degrees Fahrenheit to facilitate the incorporation by ordinary agitation or mixing" (Page 1, line 60). As such, it is clear that Hatmaker prefers that the liquid milk should be warmed, and thus clearly teaches away from the present invention wherein it is taught that the process should and can be conducted at much lower temperatures.

Hatmaker does describe the avoidance of unnecessary boiling of the milk to avoid flavour issues, but still clearly describes that some heating is desirable.

In practice, a large diary utilizing the process of the present invention with a variety of different, non-natural milk products (e.g. skim milk, etc.) which are stored at cool temperatures, the knowledge that "fresh warm natural milk" is not required, and that heating of the liquid milk is also not required to effect the desired result, would provide much greater acceptance of the process of the present invention.

The process described herein also would provide significant cost savings, and would greatly improve the flexibility of the mixing process, while reducing the risk of product degradation as a result of unnecessary heating which would be present in the Hatmaker process.

The Applicant does not dispute that the FDA papers describe the definitions of various types of dairy products, and defines the levels of milk solids, milk fats and the like. These values are well known in the dairy industry. It is also well known that milk or milk mixtures can be pasteurized, homogenized, and/or packaged using various techniques well known in the industry. However, this knowledge would not lead the skilled artisan to modify the Hatmaker process in the manner suggested by the Examiner, since there would be no motivation for the artisan to

Page -7-

make these changes.

Accordingly, the Applicant contends that Claim 1, as amended herein, is clearly inventive over the process as described by Hatmaker, and that the additional cited prior art, in combination with Hatmaker, would not provide motivation for the skilled artisan to operate the process at the temperature values required in the Applicant's process.

As to the objection to Claim 2, the Applicant acknowledges that Hatmaker uses fresh milk. However, Hatmaker uses "fresh warm natural milk", and in no way teaches that the fresh milk can be cooled to between 2 and 25°C, before mixing with the powdered milk.

As to the objection to Claims 3 and 4, the MooMilk FAQ section does state that milk should be stored at 40°F. However, this is related only to the storage temperature of the milk and has nothing to do with the processing temperature for mixing with dried milk powder. Thus, the knowledge that milk should be stored at this temperature would not motivate or suggest to the skilled artisan that the temperature range for the process of Hatmaker could be reduced by over 60°F. As such, the combination of Hatmaker and MooMilk FAQ would clearly not lead the skilled artisan to the process of the present invention.

As to the objection to Claim 5, the Applicant contends that there is nothing to suggest to the skilled artisan that leaving a mixture of powdered milk in liquid milk, for any length of time, at the temperatures taught and claimed in the present invention, would provide a suitable condensed milk product. As the Examiner is well aware, mixing of these components is not an easy task given the complexity of this biological product. It cannot be assumed that operating the Hatmaker process at a temperature which is at least 60°F lower than that taught by Hatmaker would provide satisfactory results regardless of whether the resultant mixture was allowed to stand for a period of time. There cannot be any expectation that these modifications to the Hatmaker process would clearly work.

As to the objection to Claim 6, it is acknowledged that Hatmaker provides for agitation of the mixture. However, Claim 6 describes occasional mixing of the mixture as it is standing, and not during the addition phase of the process. Further, though, it is noted that Claim 6 is now dependent on Claim 1, and thus Claim 6 is also allowable.

As to the objection to Claim 7 and 8, the Applicant acknowledges that the various milk

Page -8-

fat and milk solid levels are well known in the art. However, with respect to Claim 8, it should be noted that the final milk fat value for the mixture can include a milk fat value of 0%. It is contended that this value is not obtainable by the Hatmaker process since Hatmaker uses "natural liquid milk" or the like, which has some milk fat content.

As to the objection to Claim 9, again it is noted that the levels of milk fat content are well known in the art. However, as in the paragraph above, it would not be obvious to the skilled artisan how to achieve a condensed milk having 0% milk fat content when utilizing the Hatmaker process.

As to the objection to Claim 10, it is acknowledged that it is known in the art to alter the favour of condensed milk by evaporation of some of the water content. Again, though, it is noted that Claim 10 is now dependent on Claim 1, and thus Claim 10 is also allowable.

As to the objection to Claim 11, it is acknowledged that it is known in the art to add sweeteners to condensed milk. However, it is again to be noted that Claim 11 is now dependent on Claim 1, and thus Claim 11 is also allowable.

## Summary

The present invention provides a process for the production of condensed milk which avoids the current practice of using water and powdered milk (as described in the application as filed), and also avoids the higher temperature process which has been described by Hatmaker. As such, the process of the present invention provides significant advantages over the current practice of the industry, or the process described by Hatmaker.

The additional prior art cited by the Examiner merely describes well known properties of milk and dairy products, and well known packaging techniques. However, none of these documents, when combined with Hatmaker, would lead the skilled artisan to the present invention since none of the cited documents would suggest or motivate the skilled artisan to operate the Hatmaker process at a lower temperature, as described and claimed in the present application.

As such, the Applicant contends that the present application is allowable.

Page -9-

It is believed that with these comments, a full and complete response to the Office Action has now been submitted. Further, it is believed that the present application is now in condition for allowance. As such, reconsideration and allowance of the present application at the earliest opportunity are respectfully solicited.

However, should there be any remaining issues, or if any issues require further clarification, the Examiner is requested to contact the undersigned by telephone in order to advance this application to allowance.

> Respectfully submitted, **Gowan Intellectual Property**

Gowan Intellectual Property 1075 North Service Road West Suite 203 Oakville, Ontario CANADA L6M 2G2

905-827-5000 F: 905-827-5087

T:

Gerald A. Gowan Per:

Registered Patent & Trade-Mark Agent

Regn. No. 37,041 - Client No. 58388 email: ggowan@gowanip.com

GAG: tim